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HOUSE . . . . . No. 109

The Commonwealth of Massachusetts

PRESENTED BY:

Stephen Kulik

To the Honorable Senate and House of Representatives of the Commonwealth of Massachusetts in General Court assembled:

The undersigned legislators and/or citizens respectfully petition for the passage of the accompanying bill:

An Act prohibiting the use of health data for marketing purposes.

PETITION OF:

NAME:	DISTRICT/ADDRESS:
Denise Provost	27th Middlesex
Gale D. Candaras	First Hampden and Hampshire
Peter v. Kocot	1st Hampshire
Elizabeth A. Malia	11th Suffolk
Frank I. Smizik	15th Norfolk
Bill Bowles	2nd Bristol
John W. Scibak	2nd Hampshire
Ellen Story	3rd Hampshire
David B. Sullivan	6th Bristol
Carl M. Sciortino, Jr.	34th Middlesex
Lori Ehrlich	8th Essex
Timothy J. Toomey, Jr.	26th Middlesex
Jennifer M. Callahan	18th Worcester
Martha M. Walz	8th Suffolk
Christine E. Canavan	10th Plymouth
Joyce A. Spiliotis	12th Essex
Steven J. D'Amico	4th Bristol
Tom Sannicandro	7th Middlesex
David P. Linsky	5th Middlesex

Steven M. Walsh	11th Essex
Jonathan Hecht	29th Middlesex
Cheryl A. Coakley-Rivera	10th Hampden
Mark V. Falzone	9th Essex
Theodore C. Speliotis	13th Essex
Susan C. Fargo	Third Middlesex
Barbara A. L'Italien	18th Essex
James Cantwell	4th Plymouth
James J. O'Day	14th Worcester District

The Commonwealth of Massachusetts

In the Year Two Thousand and Nine

AN ACT PROHIBITING THE USE OF HEALTH DATA FOR MARKETING PURPOSES.

Be it enacted by the Senate and House of Representatives in General Court assembled, and by the authority of the same, as follows:

SECTION 1. Chapter 118G is hereby amended by inserting after section 33 the following section:—

Section 34. (a) As used in this section the following words shall, unless the context clearly requires otherwise, have the following meanings:—

"Bona-fide clinical trial", any research project that prospectively assigns human subjects to intervention and comparison groups to study the cause and effect relationship between a medical intervention and health outcome, has received approval from an appropriate Institutional Review Board, and has been registered at ClinicalTrials.gov prior to commencement.

"Identifying information", information that can be used to directly or indirectly identify the patient or the prescriber, including, but not limited to, a person's name, address, telephone number, facsimile number, electronic mail address, photograph or likeness, account, credit card, medical record, social security number, Drug Enforcement Agency (DEA) number, National Provider Identifier (NPI) or any other unique number, characteristic, code or information which is likely to lead to the identification of the patient or prescriber.

"Marketing purpose" means any activity by a company making or selling prescribed products, or such company's agent, intended to influence prescribing or purchasing choices of its products, including but not limited to:

(1) advertising, publicizing, promoting or sharing information about a product;

(2) identifying individuals to receive a message promoting use of a particular product, including but not limited to an advertisement, brochure, or contact by a sales representative;

(3) planning the substance of a sales representative visit or communication or the substance of an advertisement or other promotional message or document;

(4) evaluating or compensating sales representatives;

(5) identifying individuals to receive any form of gift, product sample, consultancy, or any other item, service, compensation or employment of value;

(6) advertising or promoting prescribed products directly to patients.

"Person", any business, individual, corporation, union, association, firm, partnership, committee, or other organization, individual or group of persons.

"Pharmacy", a facility under the direction or supervision of a registered pharmacist which is authorized to dispense controlled substances, including but not limited to retail drug business as defined in Section 1 of Chapter 94C.

"Prescribed product", includes a biological product as defined in section 251 of the Public Health Service Act, 42 U.S.C. §262 and a device or a drug as defined in section 201 of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §321.

"Prescriber", a person who is licensed, registered or otherwise authorized to prescribe and administer drugs in the course of professional practice.

"Regulated transaction", a prescription for a drug that is written by a prescriber within the commonwealth or that is dispensed within the commonwealth. The commonwealth does not regulate activities that take place wholly outside of the commonwealth.

(b) No person shall license, use, sell, or transfer for any marketing purpose, prescribed product information related to a regulated transaction that has identifying information. A record of a regulated transaction containing individual identifying information may be transferred to another entity, including to another branch or subsidiary of the same firm, only if it carries satisfactory assurance that the recipient will safeguard the records from being disclosed or used in the commonwealth for marketing purposes

(c) Nothing in this section shall prohibit the collection use, transfer, or sale of prescribed product information for marketing purposes if:-- (i) the data is aggregated; (ii) the data does not contain identifying information; and (iii) the data cannot be used, directly or indirectly, to obtain identifying information.

(d) Nothing in this section shall prohibit the collection, use, transfer, or sale of prescribed product information for non-marketing purposes, including, but not limited to, pharmacy reimbursement, prescription drug formulary or prior authorization compliance, patient care, patient care management, utilization review, health care research, bona fide clinical trials, product safety studies, transfer of prescription records that may occur when a pharmacy's ownership is changed or transferred, transfer of information to the patient or patient's authorized representative, and as required by law.

(e) Nothing in this section shall be interpreted to regulate conduct that takes place wholly outside of the commonwealth.

(f) Nothing in this section shall be interpreted to regulate the content, time, place or manner of any discussion between a prescriber and patient, or a prescriber and any person representing a prescription drug manufacturer.

(g) Any person who knowingly fails to comply with the requirements of this section shall be subject to an administrative penalty of at least $10,000 per violation and not more than $50,000 per violation, as assessed by the division of health care finance and policy. Each unauthorized disclosure shall constitute a violation.

(h) A violation of this section shall also constitute an unfair or deceptive act or practice in the conduct of trade in violation of Section 2 of Chapter 93A. Any person whose rights under this section have been violated may institute and prosecute in his own name and on his own behalf, or the attorney general, acting on behalf of the commonwealth, may institute a civil action for injunctive and other equitable relief.

(i) If any provision of this act or its application to any person or circumstance is held invalid, the remainder of the act or the application of the provision to other persons or circumstances is not affected.

SECTION 2. This act shall take effect upon passage.